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NOTICE OF ALLOWANCE AND FEE(S) DUE

22504 7590 02/28/2008

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 02/28/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/234,208	01/20/1999	JONI KRISTIN DOHERTY	49321-1	6406

TITLE OF INVENTION: HER-2 BINDING ANTAGONISTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$0	\$0	\$720	05/28/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

**Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

22504 7590 02/28/2008

**DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045**

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE-FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	YES	\$720	\$0	\$0	\$720	05/28/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
HOLLERAN, ANNE L.	1643	514-002000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/147; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

1

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2

3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY AND STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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EXAMINER

HOLLERAN, ANNE L.

ART UNIT

PAPER NUMBER

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DATE MAILED: 02/28/2008

Determination of Patent Term Extension under 35 U.S.C. 154 (b)

(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

09/234,208

Examiner

ANNE L. HOLLERAN

Applicant(s)

DOHERTY ET AL.

Art Unit

1643

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERIT IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/21/2007.
2. ☒ The allowed claim(s) is/are 1-3,8-10,18-20 and 27-30.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 20080208.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: All rejections under 35 USC 112, first paragraph are withdrawn.

1. The rejection of claims 1-3, 8-10, 18-20 and 29-30 under 35 USC 112, first paragraph for lack of enablement with respect to fragments is withdrawn in view of applicant's persuasive arguments.
2. The rejection of claims 18-20 and 29-30 under 35 USC 112, first paragraph for lack of enablement with respect to pharmaceutical compositions is withdrawn in view of applicant's persuasive arguments.
3. The rejection of claims 8-10, 18, and 29-30 under 35 USC 112, first paragraph, for lack of written description with respect to the limitation of 10^8M^{-1} binding affinity for binding to the ECD of HER2 for polypeptides comprising SEQ ID NO: 2 or comprising fragments of SEQ ID NO: 2 is withdrawn upon further consideration, and in view of applicant's persuasive arguments.

In the Office action mailed 11/03/2005, claims 8-10, 18, 29 and 30 were rejected under 35 USC 112, first paragraph on the grounds that the specification did not contain a written description of the claimed invention. The statement was made in that Office action that the specification and the claims as originally filed failed to contain literal support for the limitation of a polypeptide comprising SEQ ID NO: 2 or comprising fragments of 80-419 contiguous amino acids where the C-terminal 79 amino acids are present, and having binding affinity with a constant of 10^8M^{-1} . The Office action also stated that the subject matter in claims 8-10, 18, 29 and 30 broadens the scope of the invention as originally disclosed in the specification.

The claims in question are drawn to isolated polypeptides, or pharmaceutical compositions thereof, comprising the amino acid sequence of SEQ ID NO: 2 or a fragment of SEQ ID NO: 2 of about 80 to 419 contiguous residues in length, where the C terminal 79 contiguous amino acids are present, wherein at least one N-linked glycosylation site is present, and wherein the polypeptide binds to the extracellular domain (ECD) of HER-2 with an affinity binding constant of at least 10^8M^{-1} .

With respect to whether the binding affinity limitation is an amendment that broadens the scope of the claims as originally filed, applicant's arguments are persuasive, because the addition of the binding affinity limitation is a narrowing amendment.

Furthermore, with respect to whether the specification contains the requisite support for the amendment, applicant's arguments are found persuasive, because the binding affinity limitation is found in the specification and is associated with a generic concept of the invention, polypeptides comprising SEQ ID NO: 1 or polypeptides comprising fragments of 50-79 contiguous amino acids of SEQ ID NO: 1. The specification describes SEQ ID NO: 2 and SEQ ID NO: 1. SEQ ID NO: 2 encompasses SEQ ID NO: 1, which is the C-79 terminal amino acids of SEQ ID NO: 2. Thus, polypeptides comprising SEQ ID NO: 2, or comprising fragments of 80-419 contiguous amino acids where the C-terminal 79 (i.e. SEQ ID NO: 1) is present, are a subgenus of polypeptides comprising SEQ ID NO: 1. Because the binding affinity limitation is associated with the generic contemplation of the invention polypeptides and because of the overlap in scope between SEQ ID NO: 1 and SEQ ID NO: 2, the amendment of the claims reciting SEQ ID NO: 2 to include the binding affinity limitation does not constitute the

introduction of new matter into the specification as originally filed. Therefore, the rejection is withdrawn.

4. The rejection of claims 8-10, and 18 under 35 USC 112, first paragraph, for lack of written description with respect to the limitation of having at least one N-linked glycosylation site is withdrawn in view of applicants' arguments demonstrating that support is found in the specification for this limitation (see page 5, lines 19-20 of the specification). In the description of Figure 1 at page 5 of the specification, a 79 amino acid extension following arginine 340 of the Her-2 extracellular domain is taught and the statement made that this sequence has a *consensus asparagine linked glycosylation site* (which is the same as an N-linked glycosylation site; emphasis added). The 79 amino acid extension is the C-terminal 79 amino acids present in SEQ ID NO: 2. Thus, an inherent property of the 79 C-terminal extension of SEQ ID NO: 2, which would be encompassed by fragments of SEQ ID NO: 2 of 80 amino acids and comprising the C-terminal 79 amino acids of SEQ ID NO: 2, would be a polypeptide having 1 glycosylation site. Because the specification taught fragments of SEQ ID NO: 2 that would inherently have 1 glycosylation site, the limitation of having at least 1 glycosylation site, associated with fragments of SEQ ID NO: 2, is supported by the specification.

5. The rejection of claims 18 and 30 under 35 USC 112, first paragraph, for lack of written description, with respect to "combinations thereof, with the proviso that where the compositions comprises the monoclonal antibody it also comprises at least one of the agents of (a) and (b)" is withdrawn in view of applicants' persuasive arguments.

It is noted that the specification teaches at page 10, lines 3-4, the inventive pharmaceutical composition as, "comprising either or both of the inventive polypeptides and/or

monoclonal antibody". In the claims, elements (a) and (b) correspond to the inventive polypeptides. Therefore, there appears to be clear support for "combinations thereof, with the proviso that where the compositions comprises the monoclonal antibody it also comprises at least one of the agents of (a) and (b)".

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
February 14, 2008

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643